

NOV - 1 1999

**Section 3**  
**IL Test™ von Willebrand Factor - 510(k) Summary**  
**(Summary of Safety and Effectiveness)**

**Submitted by:**

Instrumentation Laboratory Company  
113 Hartwell Avenue  
Lexington, MA 02421  
Phone: 781-861-4467  
Fax: 781-861-4464

**Contact Person:**

Carol Marble, Regulatory Affairs Manager  
Phone: 781-861-4467 / Fax: 781-861-4464

**Summary Prepared:**

August 11, 1999

**Name of the Device:**

IL Test™ von Willebrand Factor

**Classification Name(s):**

864.7290	Factor Deficiency Test	Class II
81GGP	Test, Qualitative and Quantitative Factor Deficient	

**Identification of predicate device(s):**

K860371 Asserachrom® vWF

**Description of the device/intended use(s):**

IL Test™ von Willebrand Factor is an *in vitro* diagnostic automated latex enhanced immunoassay for the quantitative determination of von Willebrand Factor Antigen (vWF:Ag) in human citrated plasma on IL Coagulation Systems. When a plasma containing vWF:Ag is mixed with the Latex Reagent and the Reaction Buffer, the coated latex particles agglutinate. The degree of agglutination is directly proportional to the concentration of vWF:Ag in the sample and is determined by measuring the decrease of transmitted light caused by the aggregates (turbidimetric immunoassay).

**Statement of Technological Characteristics of the Device Compared to Predicate Device:**

IL Test™ von Willebrand Factor is substantially equivalent to the commercially available predicate device (Asserachrom® vWF) in performance and intended use.

### Section 3

## IL Test™ von Willebrand Factor - 510(k) Summary (Cont.) (Summary of Safety and Effectiveness)

### Summary of Performance Data:

In method comparison studies evaluating 120 citrated plasma samples with vWF:Ag levels ranging from 0.3% to 634.3% on an ACL 6000 and an ACL Futura, the slopes and correlation coefficients (r) for IL Test™ von Willebrand Factor versus the predicate device are shown below:

IL System	<u>%vWF:Ag</u>	
	Slope	r
ACL Futura	1.03	0.997
ACL 6000	1.00	0.996

Within run precision assessed over multiple runs using both three levels of control plasma gave the following results:

	Normal	<u>%vWF:Ag</u>	
		Abnormal Level I	Abnormal Level II
<b>ACL Futura</b>	<b>Level</b>		
Mean	99.50	79.45	35.54
% CV	3.51	2.48	3.16

	Normal	<u>%vWF:Ag</u>	
		Abnormal Level I	Abnormal Level II
<b>ACL 6000</b>	<b>Level</b>		
Mean	101.52	80.83	33.67
% CV	1.41	1.25	2.18



DEPARTMENT OF HEALTH & HUMAN SERVICES

NOV - 1 1999

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

Ms. Carol Marble  
Regulatory Affairs Manager  
Instrumentation Laboratory Company  
113 Hartwell Avenue  
Lexington, Massachusetts 02421

Re: K992704  
Trade Name: IL Test™ von Willebrand Fractor  
Regulatory Class: II  
Product Code: GGP  
Dated: August 11, 1999  
Received: August 12, 1999

Dear Ms. Marble:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895.

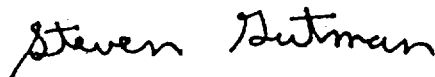
A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive, slightly slanted style.

Steven I. Gutman, M.D, M.B.A.  
Director  
Division of Clinical  
Laboratory Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use Statement

510(k) Number (if known): K992704

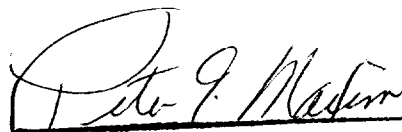
Device Name: IL Test™ von Willebrand Factor

### Indications for Use:

IL Test™ von Willebrand Factor is an *in vitro* diagnostic automated latex enhanced immunoassay for the quantitative determination of von Willebrand Factor Antigen (vWF:Ag) in human citrated plasma on IL Coagulation Systems. When a plasma containing vWF:Ag is mixed with the Latex Reagent and the Reaction Buffer, the coated latex particles agglutinate. The degree of agglutination is directly proportional to the concentration of vWF:Ag in the sample and is determined by measuring the decrease of transmitted light caused by the aggregates (turbidimetric immunoassay).

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of Clinical Laboratory Devices

510(k) Number

K992704

Prescription Use ☒  
(Per 21 CFR 801.019)

OR

Over-The-Counter Use ☐